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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,313	12/16/2003	Thomas A. Osborne	8627-454	5951

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EXAMINER
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REICHLE, KARIN M

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/737,313	Applicant(s) OSBORNE ET AL.	
	Examiner Karin M. Reichle	Art Unit 3761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2006 and 17 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/05 and 7/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

#### ***Drawings***

1. The drawings were received on 5-17-06. These drawings are approved by the Examiner.

#### ***Description***

2. The disclosure is objected to because of the following informalities: In paragraph 45, line 2, "H2 should be --H2'--.

Appropriate correction is required.

#### ***Claim Objections***

3. Claims 1-9 are objected to because of the following informalities: in claim 1, line 5, "a", first occurrence, should be deleted. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-8 and 10-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsumoto et al '665.

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Claims 1 and 4: See Figures, especially 24A-24B, col. 1, lines 6-10, col. 2, lines 20-28, col. 4, line 64-col. 6, line 9, col. 14, lines 29-42, col. 15, line 63-col. 16, line 2 and col. 18, lines 12-46 of '665, e.g. '665 teaches a medical instrument 10 comprising a housing 11 and 12 having a passage 14 through which a catheter is received, a valve body, 16, 80, 120, 130, or 140, mounted in the passage, the valve having two opposing planar faces and a peripheral edge separating the faces, see, e.g., Figures 24A-B, the valve body having a first slit, 131 or 132, that opens in one of the faces and a second slit, 132 or 131, that opens in the other face and each slit extends partly through the valve body and intersects the other slit therewithin. As disclosed at the cited portions, the valve body conforms to the outer wall of the catheter when the latter penetrates the intersection of the slits to maintain a fluid tight seal therebetween. The valve body, e.g. 130, has first and second planar dimensions, e.g., the longitudinal dimension and transverse dimension, the latter of which is less than the former when the valve body is unstressed before being mounted in the passage. It is noted that the claim does not require the valve body be stressed after being mounted nor any particular first and second dimension. With regard to the added recitation of the first and second dimensions being across the face and through the center, see Figures 24A and B and the discussion supra. With regard to the last two lines of claim 1, i.e. "the valve body...housing", see Figures 3-4 and 24A-B as well as, e.g., col. 5, lines 15-18. Therefore, while the '665 does not explicitly teach the valve body having a generally circular shape when mounted in the passage of the housing, there is sufficient factual evidence for one to conclude that the flexible elastomeric valve body of Figures 24A-B would inherently assume or have a generally circular shape when mounted in the circular passage of the circular housing, see MPEP 2112.01.

Claims 2-3: see Figures cited supra.

Claim 5: see, e.g., col. 5, lines 8-14, i.e. the housing has a recess with a dimension between 11 and 12 which is less than the thickness of the valve body which thickness is less than the first planar dimension, i.e. the length or diameter of the valve body. It should also be noted the Figures show the valve disc having the same diameter as the recess and the valve body 130 having at least a length greater than the diameter of the circular valve body.

Claim 6: see discussion of claim 5, i.e. the valve body due to the clamping is compressed when the valve body is received within the recess and it is compressed along the first planar dimension, i.e. at least those portions between 11 and 12. Again note that it is not claimed that the compression is along the entire first dimension. However also note the discussion of the valve body 130 supra with respect to claim 5.

Claims 7-8: see Figures 3-4 and 24A-B.

Claims 10-17: see discussion of claims 1-8 supra.

6. Claims 19-20, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller '033.

It is noted that the effective filing date of claims 19-26 is 10-24-95.

Claim 19: See Figures 1 and 8, and col. 2, lines 23-42, and col. 5, line 61-col. 6, line 26 of '033, e.g. '033 teaches a medical instrument 11 comprising a housing 19, 26 having a passage 23 through which a catheter is received, a valve body, 121 mounted in the passage, the valve having two planar faces and a peripheral edge separating the faces, see, e.g., Figure 8, the valve body having a slit, 134, that defines a slit plane extending from a first face, an opening, i.e. from the line above 136 downwards, extending from the second face and partly through the valve

body to intersect with the slit therewithin and internal ring 136. As disclosed at the cited portions, the valve body conforms to the outer wall of the catheter when the latter penetrates the slit plane and ring to maintain a fluid tight seal therebetween. The valve body, e.g. 121, has first and second planar dimensions, i.e. the circular valve body has a first dimension, e.g. the diameter, and a second dimension, e.g. the thickness, the latter of which is less than the former when the valve body is unstressed before being mounted in the passage. It is noted that the claim does not require the valve body be stressed after being mounted nor that the first planar dimension and second planar dimension are dimensions of any particular part of the valve body, e.g. of one of the planar faces.

Claim 20: see the portions cited supra, i.e. the housing has a recess with a dimension between 28 and 29 which is less than the thickness of the valve body which thickness is less than the first planar dimension, i.e. the length or diameter of the valve body.

Claim 22: see col. 2, lines 30-35.

Claim 25: the portion above the solid line above 136 in Figure 8 which includes 84.

7. Claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Behnke et al '034.

It is noted that the effective filing date of claims 19-26 is 10-24-95.

Claim 19: See Figures 3 and 7, and col. 1, lines 5-7, col. 3, lines 19-33 and col. 6, lines 11-48 of '034, e.g. '034 teaches a medical instrument 10A comprising a housing 16A having a passage 20A through which a cannula, i.e. a catheter, is received, a valve body, 22A mounted in the passage, the valve having two planar faces and a peripheral edge separating the faces, see, e.g., Figure 7, the valve body having a slit, 30A, that defines a slit plane extending from a first

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face, an opening 28A extending from the second face and partly through the valve body to intersect with the slit therewithin and internal ring adjacent 32A. As disclosed at the cited portions, the valve body conforms to the outer wall of the cannula, i.e. the catheter, when the latter penetrates the slit plane and ring to maintain a fluid tight seal therebetween. The valve body, e.g. 121, has first and second planar dimensions, i.e. the circular valve body has a first dimension, e.g. the diameter at the first planar face or top surface, and a second dimension, e.g., the diameter at the second planar face or lower surface, the latter of which is less than the former when the valve body is unstressed before being mounted in the passage, see Figure 3. It is noted that the claim does not require the valve body be stressed after being mounted nor that the first planar dimension and second planar dimension are dimensions of any particular part of the valve body.

Claim 20: see the portions cited supra, i.e. the housing has a recess with a diameter which is less than the diameter of the valve body adjacent the first planar face.

Claims 21-22: see the cited portions of '033.

### ***Claim Rejections - 35 USC § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al '665.

Applicants claim the peripheral edge has an oval shape when the valve body is unstressed before being received in the recess, i.e. a shape which is longer along one axis than the other.

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While '665 does not teach an oval shape, it does teach a shape which is longer along one axis than the other in combination with a circular recess, see Figures 3-4 and 24A-B. Furthermore, see paragraphs 42, 66 and 70 and Figures of the instant application, i.e. no disclosure of the criticality of the oval shape over any other shape which has one axis longer than the other axis, e.g. a rectangle or the shape shown in Figures 11-12, i.e. just one of numerous shapes for the purpose of providing a shape having different dimensioned axes, and note that claim 9 does not require the valve body be stressed or compressed (However note the discussion of claims 5-6 supra). Therefore, it would be an obvious matter of design choice to employ an oval rather than a rectangle on the '655 device since such modification would have involved a mere change in the shape of the component. A change in shape is generally recognized as being within the level of ordinary skill in the art, i.e. an oval is just one of numerous configurations a person of ordinary skill in the art would find obvious for the purpose of providing a shape having different dimensioned axes, In re Dailey 149 USPQ 47.

10. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Behnke et al '034 in view of Thomas et al '463.

Applicant claims the peripheral edge being noncircular when the valve body is unstressed before being received in the recess, and more specifically having an oval shape, i.e. a shape which is longer along one axis than the other. While '034 does not teach an oval shape, it does teach a valve body sized with respect to the recess such that the valve body is compressed about the periphery adjacent the slit to ensure closing of the slit, see cited portions of '034. Furthermore, see '463 at col. 4, line 31-col. 5, line 12, i.e. interchangeability of a valve body sized with respect to a recess such that the valve body is compressed about the periphery to



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ensure closing of the slit with a valve body having an oval peripheral edge such that the valve body is compressed to ensure closing of the slit. Therefore, to make the valve body of '034 of oval shape instead would be obvious in view of the interchangeability as taught by '463.

### ***Double Patenting***

11. Applicant is advised that should claims 1 and 10 be found allowable, claims 4 and 13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

See claim 1, lines 6-10 and similar language in claim 10, and, e.g., paragraph 40, last sentence and compare to claims 4 and 10.

### ***Terminal Disclaimer***

12. The Terminal Disclaimers filed 2-25-06 have been approved.

### ***Response to Arguments***

13. Applicant's remarks of 2-25-06 have been carefully considered but are either deemed moot, e.g. the matters of form, in that such issues have not been repeated or are deemed not persuasive, i.e. the prior art rejections. Specifically with regard to the prior art rejections, such arguments are deemed narrower than the teachings of Matsumoto et al as discussed supra and Applicant's mere conclusion that such reference does not teach the claimed shape when mounted

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in the passage, e.g. what is Applicant's support for such statement?, and narrower than the claim language and the teachings of Miller and Behnke, i.e. the dimensions are not defined to overcome the dimensions taught by the references as discussed supra.

### ***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

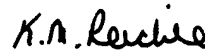
Any new grounds of rejection were necessitated by the amendments to the independent claims.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Karin M. Reichle  
Primary Examiner  
Art Unit 3761

KMR  
July 29, 2006